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REQUEST FOR CERTIFICATE OF
CORRECTION UNDER 37 CFR 1.322
Docket No. OAV-100
Patent No. 6,834,652

Margaret Efron, Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Sanford D. Altman
Issued : December 28, 2004
Patent No. : 6,834,652 ✓
For : Catheter Protective Shield

Mail Stop Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION
UNDER 37 CFR 1.322 (OFFICE MISTAKE)

Sir:

A Certificate of Correction (in duplicate) for the above-identified patent has been prepared and is attached hereto.

In the left-hand column below is the column and line number where errors occurred in the patent. In the right-hand column is the page and line number in the application where the correct information appears.

Patent Reads:

(57) Abstract, line 3:
"shield includes"

Column 6, line 17:
"to the skin inner bag"

Application Reads:

Page 10, line 2:
--shield comprises--

Page 9, line 10:
--to the skin said inner bag--

Column 6, line 30:
“said outer and”

Amendment dated August 26, 2003 (original
claim 16), line 23:
--said outer cover and--.

A true and correct copy of pages 9 and 10 of the specification as filed which supports Applicants' assertion of the errors on the part of the Patent Office accompanies this Certificate of Correction.

Approval of the Certificate of Correction is respectfully requested.

Respectfully submitted,



Margaret Efron
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MHE/ems

Attachments: Certificate of Correction in duplicate; copy of pages 9 and 10 of the specification;
Copy of Amendment dated August 26, 2003

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,834,652

Page 1

DATED : December 28, 2004

INVENTOR : Sanford D. Altman

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

(57) Abstract,

Line 3, "shield includes" should read --shield comprises--.

Column 6,

Line 17, "to the skin inner bag" should read --to the skin said inner bag--.

Line 30, "said outer and" should read --said outer cover and--.

MAILING ADDRESS OF SENDER:

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PATENT NO. 6,834,652

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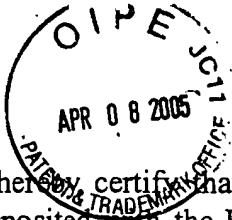


15. A protective shield comprising:

- a) an inner bag comprising an opening and an absorbent material, wherein said absorbent material is affixed within said opening and said absorbent material is formed for receiving a proximal end of a catheter projecting through the skin, said opening comprises a means for adhering said opening to the skin, such that a protective seal can be formed between said inner bag and the skin; and
- b) an outer cover comprising a flexible sheet having a peripheral edge, wherein said peripheral edge comprises means for adhering said peripheral edge to the skin, such that a protective seal can be formed between said peripheral edge and the skin, wherein when said outer cover is adhered to the skin said inner bag is sealed beneath said outer cover, within said peripheral edge.

Abstract of the Disclosure

[0037] This subject invention is a protective shield for protecting indwelling medical devices, during showering, bathing, or swimming. This protective shield comprises an inner bag having an opening containing by a medical grade absorbent material, where the opening is surrounded by a medical grade adhesive for attachment to a patient's skin. The medical device is inserted into the bag through the absorbent material. This bag is covered by an attached outer cover, which has an adhesive material applied along its peripheral edge or attachment to the patient, which diverts the flow of fluid away from the opening of the inner bag. The absorbent material in opening of the inner bag traps and holds fluid penetrating the two adhesive barriers affording additional level of protection in preventing fluid from reaching the inside of the pouch.



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AMENDMENT UNDER 37 CFR §1.111
Examining Group 3764
Patent Application
Docket No. OAV-100
Serial No. 09/941,012

August 26, 2003

Margaret Efron

Margaret Efron, Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Michael Brown
Art Unit : 3764
Applicant : Sanford D. Altman
Serial No. : 09/941,012
Filed : August 28, 2001
Confirm. No. : 6194
For : Catheter Protective Shield

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT UNDER 37 CFR §1.111

Sir:

In response to the Office Action dated July 3, 2003, please amend the above-referenced patent application to read as follows:

In the Claims

1 (currently amended). A protective shield for providing a ~~moisture~~protective barrier around the puncture site of an indwelling catheter comprising:

a) an inner bag having at least one opening for placement over the catheter, wherein said opening comprises absorbent material affixed within, said absorbent material formed for receiving an exposed end of the catheter, said inner bag further comprising an adhesive substantially surrounding said opening for attachment to the skin, such that a protective seal can be formed between said inner bag and the skin; and

b) an outer cover comprising a flexible sheet having adhesive about a peripheral edge for adhering to the skin over said inner bag such that said inner bag is sealed beneath said outer cover forming a protective seal.

2 (original). The protective shield according to claim 1, wherein said inner bag and said outer cover are made from a flexible, fluid impermeable material.

3 (original). The protective shield according to claim 2, wherein said flexible, fluid impermeable material is plastic, polymer, silicon, vinyl, latex, or rubber.

4 (original). The protective shield according to claim 1, wherein said inner bag and said outer cover are made from a material substantially impervious to infectious agents.

5 (original). The protective shield according to claim 1, wherein said inner bag comprises an annular ring integrally formed with said opening.

6 (original). The protective shield according to claim 1, wherein said outer cover comprises an annular ring integrally formed with said peripheral edge.

7 (original). The protective shield according to claim 1, wherein said adhesive is a medical grade adhesive for application to the skin.

8 (original). The protective shield according to claim 1, where in said adhesive is a moisture resistant adhesive.

9 (original). The protective shield according to claim 1, wherein said adhesive comprises a removable strip for protecting said adhesive prior to use.

10 (original). The protective shield according to claim 1, wherein said absorbent material comprises a slit formed for receiving the exposed end of the catheter.

11 (original). The protective shield according to claim 1, wherein said absorbent material is an absorbent paper, absorbent fiber, or absorbent cloth.

12 (original). The protective shield according to claim 1, wherein said inner bag is affixed to said outer cover.

13 (currently amended). A protective shield for protecting an indwelling catheter and exit site from moisture and debris comprising:

a) a flexible, fluid-impermeable inner bag comprising a means for receiving a proximal end of a catheter projecting through the skin, said inner bag further comprising an adhesive substantially surrounding said means for receiving the proximal end for attachment to the skin, such that a protective seal can be formed between said inner bag and the skin; and

b) a flexible, fluid-impermeable outer cover comprising means for adhering said outer cover to the skin, wherein said inner bag is sealed beneath said outer cover, such that a protective seal can be formed between said outer cover and the skin.

14 (original). The protective shield according to claim 14, wherein said means for receiving a proximal end of a catheter projecting through the skin comprises an absorbent material.

15 (original). A protective shield comprising:

a) an inner bag comprising an opening and an absorbent material, wherein said absorbent material is affixed within said opening and said absorbent material is formed for receiving a proximal end of a catheter projecting through the skin, said opening comprises a means for adhering said opening to the skin, such that a protective seal can be formed between said inner bag and the skin; and

b) an outer cover comprising a flexible sheet having a peripheral edge, wherein said peripheral edge comprises means for adhering said peripheral edge to the skin, such that a protective seal can be formed between said peripheral edge and the skin, wherein when said outer cover is adhered to the skin said inner bag is sealed beneath said outer cover, within said peripheral edge.

16 (new). A protective shield for protecting an indwelling catheter and exit site from moisture and debris comprising:

a) a flexible, fluid-impermeable inner bag comprising a means for receiving a proximal end of a catheter projecting through the skin, said inner bag further comprising an adhesive substantially surrounding said means for receiving the proximal end for attachment to the skin, such that a protective seal can be formed between said inner bag and the skin; and

b) an outer cover comprising means for adhering said outer cover to the skin, wherein said inner bag is affixed to and sealed beneath said outer cover, such that a protective seal can be formed between said outer cover and the skin.

Remarks

Claims 1-15 were previously pending in the subject application. By this amendment, the applicant has amended claims 1 and 13 and added new claim 16. No new subject matter has been added by this amendment. Support for the amendments and new claim can be found throughout the subject specification including, for example, at page 5, paragraph 30. Accordingly, claims 1-16 are now before the Examiner for consideration.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be interpreted to indicate that the applicant has agreed with, or acquiesced to, the rejections set forth in the outstanding Office Action. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

The subject invention provides a unique shield for protecting indwelling catheters and corresponding exit sites from debris and moisture. The protective shield of the subject invention is particularly advantageous because of its ease of use. The subject shield has two layers of protection; a first layer in the form of an inner bag and a second protective layer in the form of an outer cover that is sized such that the inner bag can be encompassed beneath the outer cover. In use, the inner bag receives the proximal end of the catheter and is affixed by adhesive material to the user's skin to form a protective seal. The outer cover is also affixed to the user's skin by adhesive material such that the inner bag is positioned within the peripheral edges of the outer cover and a protective seal is formed between the outer cover and the user's skin. Such an arrangement provides a unique and advantageous shield because the outer cover serves as a tarp to move water and debris away from the inner bag.

Claim 13 has been rejected under 35 U.S.C. §102(b) as being anticipated by Norby *et al.* (U.S. Patent Reissue No. 29,319). To the extent this ground for rejection might be applied to the amended claim 13, the applicant respectfully traverses the ground for this rejection because the Norby *et al.* reference does not teach the current applicant's advantageous catheter shield.

Although the Norby *et al.* system and the protective shield of the current invention share certain superficial similarities, a careful comparison of the two technologies reveals critical differences. Unlike the protective shield of the subject invention, a drainage system is disclosed by

Norby *et al.* in which an opening within a sheet of substantially gelatinous material is placed over a wound/incision to cover only the external area of the body surrounding the opening, see claims 1-5 and col. 2, lines 35-50, and does not cover the incision/wound itself. A plastic cap, bag, or cover (see claims 1-5) is then removably placed over the opening of the sheet to engage with the sheet and not the patient's skin. In contrast, the inner bag and the outer cover of the subject invention are both affixed to the patient's skin to provide a dual layered protective cover that seals out moisture and debris.

Certain characteristics of the inner bag and the outer cover further distinguish the currently claimed protective shield from the drainage system of Norby *et al.* The subject protective shield is composed of a flexible, fluid-impermeable inner bag and outer cover. As noted above, the outer cover is sized to accommodate the inner bag within its peripheral edges. In Norby *et al.*, there is no teaching or suggestion of a cap, bag, or cover that is sized to accommodate the sheet nor vice versa, a sheet that is sized to accommodate the cap, bag, or cover. Further, Norby *et al.* fails to disclose or suggest placing the cap, bag, or cover over the sheet such that the sheet is sealed within the peripheral edges of the cap, bag, or cover, or vice versa. Moreover, the sheet of Norby *et al.* is substantially composed of gelatinous material as opposed to the fluid, impermeable material of the present invention. Accordingly, there is no rationale for concluding that the currently claimed protective shield is the drainage system of Norby *et al.*

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

In *Dewey & Almy Chem. Co. v. Mimex Co.*, Judge Learned Hand wrote:

No doctrine of the patent law is better established than that a prior patent . . . to be an anticipation must bear within its four corners adequate directions for the practice [of the subsequent invention] . . . if the earlier disclosure offers no more than a starting point . . . if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. 124 F.2d 986, 990; 52 USPQ 138 (2nd Cir. 1942).

Thus, the applicant respectfully submits that the drainage system described by Norby *et al.* in no way teaches or suggests the protective shield claimed by the current application, which provides (1) two layers of protection for an indwelling catheter and exit site using an inner bag and outer cover, (2) an inner bag and outer cover composed of flexible, fluid impermeable material, and (3) sealing the inner bag beneath the outer cover such that a protective seal is formed between the outer cover and the user's skin. Because Norby *et al.* does not disclose such a protective shield, the applicant's respectfully request reconsideration and withdrawal of the rejection of claim 13 under 35 U.S.C. §102(b).

Claim 14 has been objected to as being dependent on rejected base claim 13. As discussed above, the applicant respectfully submits that the anticipation rejection of claim 13 is improper because the Norby *et al.* does not disclose, within its four corners, a protective shield having the characteristics recited in the current claim 13. Accordingly, reconsideration and withdrawal of this objection is respectfully requested.

In view of the foregoing remarks and amendment, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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